UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS END-PAYOR ANTITRUST LITIGATION

No. 13-CV-9244 (RA)

OPINION AND ORDER

RONNIE ABRAMS, United States District Judge:

This case concerns whether Defendants Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Development Center Americas, Inc. (collectively "Takeda") are liable to the indirect purchasers of Takeda's diabetes medication called ACTOS ("End-Payor Plaintiffs" or "EPPs"), for unlawfully inflating that drug's prices in violation of state antitrust laws. In September 2015, this Court granted Defendants' motion to dismiss. *See* Op. & Order re: Mot. to Dismiss ("2015 Op.") at 51 (Dkt. 221), *available at* 2015 WL 5610752 ("*Actos I*"). On appeal from that decision, the Second Circuit largely affirmed the dismissal, except with respect to Takeda's two monopolization claims, which were remanded to proceed on a narrower theory. *See In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 102 (2d Cir. 2017) ("*Actos II*"). Following remand, EPPs moved for leave to amend, seeking to add new allegations concerning causation, which the Court granted in part and denied in part. EPPs then filed the operative Fourth Consolidated Amended Complaint ("Complaint"). Now before the Court is Takeda's motion to dismiss. For the following reasons, the motion is denied.

BACKGROUND

Both this Court and the Second Circuit have recounted this case's factual background and explained the relevant regulatory scheme at length. *See In re Actos*, 848 F.3d at 93–97; 2015 Op. at 1–16. For the purposes of this Opinion, the Court assumes the reader's familiarity with the case and will restate only those facts relevant to resolving Takeda's motion.

I. Regulatory Background

The issues in this case largely revolve around the proper interpretation of a provision of the Hatch-Waxman Act (the "Act"), which controls how and when manufacturers of brand name drugs, and their generic counterparts, can lawfully enter the market. Normally, inventors obtain patents for their brand-name drugs. Patents that protect a drug may include claims directed to: (1) a single active ingredient of the drug, that is, a chemical compound, referred to in the Act's supporting regulations as a "drug substance" claim; (2) multiple active ingredients of the drug, that is, a chemical composition, referred to as a "drug product" claim; or (3) a method of using the drug, referred to as a "method-of-use" claim.

Inventors must get FDA approval to lawfully sell their drugs. To do so, they must file New Drug Applications (NDAs) with the FDA. When filing an NDA that seeks approval to market a particular brand drug, inventors are required to submit information concerning related patents. The scope of one of the Act's provisions governing when (and what) information about such patents must be submitted with an NDA is at the heart of this case.

For each patent that is submitted as part of an NDA, the applicant must describe the patent as a drug substance, drug product, or method-of-use patent, depending on the nature of the claims included in each patent. *See In re Actos*, 848 F.3d at 98–99. When an NDA is approved, the patent

description and other information submitted with the application is listed in conjunction with the NDA number and the drug name, among other things, in the FDA's so-called "Orange Book."

If generic-drug manufacturers wish to sell a generic version of a brand-name drug they must first file with the FDA an Abbreviated New Drug Application (ANDA). Any ANDA must contain "an appropriate certification" for each patent listed in connection with the NDA in the Orange Book. If the generic-drug manufacturer intends to market a drug before a listed patent has expired, then it must tell the FDA that the generic will either not infringe the brand's patents, or that the brand's patents are invalid. Under the Act, there are two primary ways by which generics can do so.

First, generics can certify that the brand's patents are "invalid or will not be infringed by" their generic, which is referred to as a "Paragraph IV certification." *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Because the Act provides that the filing of a Paragraph IV certification constitutes an act of infringement, the brand may then sue the generic accordingly. To incentivize generic manufacturers to challenge invalid patents (and therefore run the risk of being sued by patent holders), the first generic to file a Paragraph IV certification may receive a 180-day period during which it has the exclusive right to market a generic version of the drug. *See id.* § 355(j)(5)(B)(iv). This exclusivity period can be very lucrative for the generics who successfully challenge patents.

Second, if the generic is seeking to market only a new *method of using* a drug, it can "carve out" any patented methods of use in its proposed label for the drug and proceed with a lower risk of a patent-infringement lawsuit by submitting a so-called Section viii statement. *Id.* § 355(j)(2)(A)(viii) ("Section viii statement"). Successful applications that carve out patented methods of use under Section viii allow generics to enter the market even during the 180-day

exclusivity period held by the first successful Paragraph IV filer. *See In re Actos*, 848 F.3d at 95. If a patent submitted with an NDA includes *both* drug substance or drug product claims, in addition to method-of-use claims, the generic can either file an ANDA with Paragraph IV certifications as to all claims, or they can file one with a so-called "split certification." In a split-certification, the generic submits a Paragraph IV certification as to the drug substance and/or drug product claims, and Section viii statements as to the claims covering the patented methods of use that it intends to carve out from its label.

II. Factual Background

Starting in the 1980s, Takeda obtained several patents related to its diabetes medicines. The first of those patents, U.S. Patent. No. 4,687,777 (the "'777 patent"), claimed the compound "pioglitazone," the active ingredient in Takeda's brand-name drug ACTOS. Takeda later obtained two other patents—U.S. Patent Nos. 5,965,584 (the "'584 patent") and 6,329,404 (the "'404 patent")—which claimed compositions of pioglitazone combined with other drugs and methods of using those compositions. To obtain FDA approval to sell ACTOS, Takeda filed a New Drug Application (NDA) in January 1999, in which it submitted information regarding the '777 patent and described it as a drug substance patent. The FDA approved the NDA in July 1999 and listed the '777 patent in the Orange Book. Later in 1999, and then in 2002, Takeda submitted information with respect to the '584 and '404 patents, respectively, in connection with the ACTOS NDA, describing those two patents (hereinafter "the Patents") as both drug product patents and method-of-use patents (and improperly so, in EPPs' view). Those patents were also subsequently listed in the Orange Book for the ACTOS NDA. At the time, however, the Orange Book was only capable of displaying one description per patent listed. Thus, although the Patents were described to the

FDA as both drug product patents and method-of-use patents, the Orange Book listings displayed only that they were described as method-of-use patents until starting in 2003.

At the start of 2003, several generics also began applying to enter the ACTOS market upon the expiration of the '777 patent, which would occur on January 17, 2011. The first four companies—Mylan Pharmaceuticals, Inc., Alphapharm (together, "Mylan"),[1] Watson Laboratories, Inc., now known as Actavis PLC ("Actavis"), and Ranbaxy Laboratories, Inc. ("Ranbaxy")—who sought to compete with ACTOS filed their applications on the same day. These generics, the so-called first filers, challenged the validity and potential for infringement of the Patents with respect to their proposed ACTOS generics by submitting Paragraph IV certifications as to the Patents' drug product claims. They also submitted Section viii statements with respect to the Patents' method-of-use claims, seeking to market ACTOS for uses not covered by those patents. Over the following years, six other generics, the later-filers, submitted similar applications with split certifications. Just one manufacturer—Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (collectively "Teva")—submitted an application including only Section viii statements with respect to the Patents' method claims (and which made no certifications as to the Patents' drug product claims). According to EPPs, Teva did not file a Paragraph IV certification as to the drug product claims because it believed that the Patents were not properly listed as drug product patents for the ACTOS NDA and that a Paragraph IV certification was therefore unnecessary.

In 2003, Takeda sued the generics who had filed applications with Paragraph IV certifications challenging the validity of the Patents. Six years later, Takeda initiated a separate infringement lawsuit against Teva. Soon thereafter, the FDA received a citizen petition from non-

[1] Mylan subsequently acquired Alphapharm in 2007. Compl. ¶ 83.

party Sandoz Inc., essentially asking it to deny Teva's ANDA on the ground that it lacked a Paragraph IV certification as to the drug product claims. Critically, as a result of that petition, Takeda informed the FDA in January 2010 that the Patents had been properly described as both drug product and method-of-use patents for the ACTOS NDA. As a matter of practice, the FDA relies on such representations without independent evaluation. *See In re Actos*, 848 F.3d at 96–97. Based on Takeda's representations, the FDA granted the citizen petition on March 15, 2010. The FDA thus required that the ACTOS ANDAs, including Teva's, contain an appropriate Paragraph IV certification for the Patents explaining why the generic did not infringe those patents' drug product claims or that those claims were invalid. *See id.* (citing FDA Resp. to Sandoz Citizen Pet., No. FDA-2009-P-0411-0010 (Mar. 15, 2010) (Weiner Decl., Ex. A (Dkt. 260-1)).

Takeda ultimately settled its infringement lawsuits on terms that allowed the first-filing generics (and Teva, to a lesser extent) to begin selling generic versions of ACTOS on August 17, 2012. That was over a year after the '777 patent expired and approximately four years before the Patents expired. The other companies could begin selling generic ACTOS 180 days later.

III. Procedural Background

On December 31, 2013, EPPs commenced this action against Takeda and several generic manufacturers, no longer part of this case, for allegedly delaying generic entry into the ACTOS drug market, among other things. On September 22, 2015, the Court dismissed EPPs' prior complaint in its entirety with prejudice. *See Actos I*, 2015 WL 5610752, at *29. EPPs then appealed the dismissal of its two monopolization claims against Takeda.

A. *Actos II*

On appeal, EPPs argued that they had plausibly alleged that Takeda's purportedly improper Orange Book listings regarding the Patents caused a delay of the generics' entry into the generic

ACTOS market, under two theories. The first theory was that Takeda's allegedly false descriptions of the Patents "forced the generics to file Paragraph IV certifications, which triggered a 180-day exclusivity period for first-filers and a corresponding 180-day delay (the 'bottleneck') for all subsequent filers." *In re Actos*, 848 F.3d at 98. The second theory was based only on Teva's delayed entry into the generic ACTOS market. Under this theory, the FDA's ruling on Sandoz's citizen petition, which required Teva to file Paragraph IV certifications as to the Patents' drug product claims, forced Teva to become subject to the 180-day bottleneck because it was not a first-filer.

The Second Circuit affirmed this Court's rejection of EPPs' first causation theory, albeit on different grounds. It held that, to succeed on this theory, EPPs were required to plausibly allege that the generics *knew* that Takeda had listed the Patents as drug product patents for the ACTOS NDA when the generics filed their Paragraph IV certifications as to those patents. Because the EPPs' Complaint lacked such allegations, EPPs could not plausibly allege that Takeda's Orange Book listings *caused* Mylan, Ranbaxy, and Actavis to file Paragraph IV certifications. As such, EPPs could also not plausibly allege that the description of the Patents as drug product patents caused the 180-day exclusivity period of Mylan, Ranbaxy, and Actavis, and the corresponding bottleneck for all subsequent filers.

The Circuit vacated this Court's decision in part, however, as to EPPs' second theory, holding that EPPs had in fact plausibly alleged that Takeda had delayed Teva's entry into the ACTOS market. The Court held that, unlike the other generic defendants, Teva filed its Paragraph IV certification directly in response to the FDA's ruling on the citizen petition, which itself was directly in response to Takeda's allegedly false representation concerning the accuracy of its patent descriptions:

> As noted, the FDA first preliminarily approved Teva's application, then entertained a citizen petition seeking to force all applicants to make Paragraph IV certifications as to the '584 and '404 patents, and then publicly announced that certifications would indeed be required. In so doing, the FDA expressly stated that certifications would be required precisely *because* Takeda had described these patents as drug product patents. In other words, the FDA made no attempt to evaluate whether the descriptions were true, but simply accepted them at face value—thus frustrating Teva's Section viii application. While Teva thereafter sought to challenge the truthfulness of these descriptions in its litigation with Takeda (but settled before the issue was resolved), the damage had been done. A plaintiff could hardly ask for a clearer causal connection.

In re Actos, 848 F.3d at 100 (emphasis in original).

In short, under the second theory, Takeda's allegedly false descriptions—as made to the FDA in response to the Sandoz citizen petition—caused the *FDA* to cause Teva to file Paragraph IV certifications as to the drug product claims of the Patents. This allegedly led Teva to settle its pending lawsuit with Takeda by a accepting a license to market an authorized-generic version of ACTOS on the earlier of August 17, 2012 or the date another generic version of ACTOS entered the market. Thus, absent Takeda's representations to the FDA that the Patents were correctly listed as drug patents for the ACTOS NDA, Teva would have stuck with its Section viii statements, and would have remained eligible for final FDA approval following the ruling on the citizen petition. As the theory goes, this would have eliminated the need for Takeda to provide Teva with a license to market an authorized generic, and Teva could instead have entered the market as soon as the '777 patent expired.

In remanding to this Court to consider the Teva theory, the Circuit further indicated that this Court should consider "in the first instance" Takeda's arguments that it had not previously addressed, including: (1) that Takeda had "correctly described the [Patents] as drug product patents under 21 U.S.C. 355(b)"; (2) that even if it incorrectly described the Patents, EPPs failed to plausibly allege that Takeda did so fraudulently and in bad faith; and (3) that, in any event, the

generics would still have been required to submit Paragraph IV certifications as to the Patents' drug product claims. *Actos II*, 848 F.3d at 101 & n. 11

B. EPPs' Post-*Actos II* Amendment

Following remand, EPPs sought to amend their Complaint to expand the Teva theory endorsed by the Second Circuit by applying it to the other generics. Under the expanded theory, Takeda's allegedly false representations to the FDA in response to the Sandoz citizen petition that Takeda's patent descriptions were accurate, caused the FDA to permit Mylan, Ranbaxy, and Actavis to maintain their Paragraph IV certifications as to the Patents' drug product claims. According to EPPs, had Takeda been honest—and only described the patents as "method-of-use patents"— Mylan, Ranbaxy, and Actavis (and all other generics with ANDAs then pending) would have been able to withdraw their Paragraph IV certifications as to the drug product claims, and address only the method-of-use claims, either with a Section viii statement or a Paragraph IV certification. And the generics, EPPs posit, "as rational profit maximizing entities," would have chosen Section viii statements for the method of use claims, to avoid Paragraph IV litigation and the resulting 30-month stay. As such, there would have been no 180-day exclusivity period and the generics could have potentially come to market as early as the expiry of the '777 patent.

In response, Takeda argued that the Second Circuit's mandate was expressly limited to Plaintiffs' theory about Teva, such that permitting EPPs to extend the theory to the other generics violated the mandate rule. The Court rejected that argument, holding that the Second Circuit's mandate was broad enough to encompass amendments that include more than one way in which the FDA's 2010 ruling harmed Plaintiffs. EPPs' motion was thus granted, to the extent the proposed amendments alleged that the FDA's ruling on the Sandoz citizen petition caused a delay in the generics' market entry. Shortly thereafter, EPPs filed the Complaint which has been

narrowed to assert just two monopolization claims (monopolization and attempted monopolization) against Takeda under state law.

LEGAL STANDARD

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557). On a Rule 12(b)(6) motion, the question is "not whether [the plaintiff] will ultimately prevail," but "whether [her] complaint [is] sufficient to cross the federal court's threshold." *Skinner v. Switzer*, 562 U.S. 521, 529–30 (2011) (internal quotation marks omitted). In answering this question, the Court must "accept[ ] all factual allegations as true, but 'giv[e] no effect to legal conclusions couched as factual allegations.' " *Stadnick*, 861 F.3d at 35 (quoting *Starr v. Sony BMG Music Entm't*, 592 F.3d 314, 321 (2d Cir. 2010)).

DISCUSSION

Pursuant to Section 2 of the Sherman Act, it is unlawful to "monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States, or with foreign nations." 15 U.S.C. § 2.[2] Plaintiffs asserting a monopolization claim must allege that the purported monopolizer: (1) possesses monopoly power in the relevant market, (2) engages in

[2] Plaintiffs do not set forth the requirements for a monopolization claim under the numerous state laws cited in the Complaint, nor do they plead any state-specific factual allegations. The Court assumes, as the parties do (and as the Second Circuit did in *Actos II*) that those statutes accord with the federal standard for purposes of this motion.

anticompetitive conduct, that is, "conduct without a legitimate business purpose that makes sense only because it eliminates competition," and (3) causes antitrust injury to the plaintiffs as a result. *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 133 (2d Cir. 2014); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d at 219 (quoting *Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc.*, 429 U.S. 477, 489 (1977)). "In order to show attempted monopolization, the plaintiff must prove: (1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 651 (2d Cir. 2015).

Takeda's monopoly power in the ACTOS drug market is undisputed. "Given that [its] monopoly power has been established, this case turns on whether [Takeda] willfully sought to maintain or attempted to maintain that monopoly in violation of § 2." *Id.* at 651. More specifically, the parties contest whether EPPs have adequately alleged that Takeda engaged in any anticompetitive conduct to begin with, and if so, whether that conduct caused an unlawful extension of Takeda's monopoly power. The Court believes it has.

I. Anti-Competitive Conduct

EPPs allege that Takeda acted anti-competitively by falsely representing to the FDA on January 22, 2010, in response to the Sandoz citizen petition, that the Patents were accurately described in the Orange Book as drug product patents for the ACTOS NDA. Under EPPs' reading of the listing statute, 21 U.S.C. § 355(b)(1), they assert that the Patents should have been described only as method-of-use patents. Takeda responds that EPPs misconstrue the listing statute. Under its reading, Takeda argues that the statute required it to describe the Patents exactly as it did—that is, as both drug product patents and method-of-use patents for the ACTOS NDA. Thus, Takeda

maintains that its statements to the FDA that those descriptions were accurate were not false or improper because they were consistent with what the statute required.

The parties' competing interpretations of 21 U.S.C. § 355(b) raise an issue of first impression: no court has yet considered whether the provision requires an NDA applicant for a drug made up of a single active compound, like ACTOS, to describe patents containing claims directed to compositions of the active compound, in combination with other active compounds, as "drug product" patents. In cases where plaintiffs have asserted antitrust claims based on defendants' allegedly improper Orange Book listings, courts have often refrained from deciding whether defendants' interpretations of the listing statute were correct as a matter of law, and have instead focused on whether those interpretations were "reasonable." *See Organon Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 460 (D.N.J. 2003) (finding that "given the statutory and regulatory language at the time," the patentee, who had submitted a patent "for listing in the Orange Book . . . had a reasonable basis for the submission" and therefore the listing was "not improper"); *In re Lantus Direct Purchaser Antitrust Litig.*, 284 F. Supp. 3d 91 (D. Mass. 2018) (dismissing antitrust claims based on allegedly improper Orange Book listings because the defendant's interpretation of the relevant FDA regulations was "not unreasonable"), *appeal filed*, No. 18-0286 (1st Cir. Nov. 2, 2018). In this case, however, the Second Circuit directed this Court to "consider such issues in the first instance," namely, whether Takeda correctly described the Patents as drug product patents under 21 U.S.C. § 355(b). The Court will, accordingly, first ascertain the proper interpretation of this provision. Although both parties make strong arguments in support of their respective readings, neither reading is entirely accurate.

1. The Parties' Competing Interpretations of "Claims"

The pertinent provision of the listing statute, section 21 U.S.C. § 355(b)(1) provides:[3]

> The [NDA] applicant shall file with the application the patent number and the expiration date of any patent which *claims the drug* for which the applicant submitted the application or which *claims a method of using such drug* and *with respect to which a claim of patent infringement could reasonably be asserted* if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

(emphasis added).[4] As previously noted, "such patents consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents." 21 C.F.R. § 314.53(b)(1).[5]

The parties' dispute over how the Court should interpret § 355(b)(1) centers around the meaning of the word "claims." EPPs argue that Takeda could not truthfully describe the Patents as "drug product" patents covering ACTOS specifically because, they maintain, the drug product claims of those Patents do not "claim[] the drug for which the applicant submitted the application," § 355(b)(1). Under EPPs' reading, to properly describe a patent as a "drug product" patent, at least one of the patent's drug product claims must contain the identical set of elements as the NDA drug. Thus, according to EPPs, because the NDA drug here, ACTOS, is indisputably made up of

[3] Unless otherwise noted, this opinion cites the here-applicable 2000 edition of Title 21 of the U.S. Code and the 2003 edition of Title 21 of the Code of Federal Regulations.

[4] Pursuant to 21 U.S.C. § 355(c)(2), when a patent issues after an NDA has already been approved, the patent must also be listed in connection with the NDA drug if the identical requirements in § 355(b)(1) are present. *See* § 355(c)(2) (providing that an NDA applicant shall file with the application "the patent number and the expiration date of any patent which *claims the drug* for which the applicant submitted the application or which *claims a method of using such drug* and *with respect to which a claim of patent infringement could reasonably be asserted* if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug") (emphasis added). EPPs state that the ACTOS NDA was approved on January 15, 1999. Compl. ¶ 62. The '584 patent issued on October 12, 1999, and the '404 patent issued on December 11, 2001. As the Patents issued after the ACTOS NDA was approved, it appears that they were actually listed by Takeda pursuant to § 355(c)(2)—not § 355(b)(1). In any event, as the substantive requirements with respect to listing are identical in these provisions, and the parties cite § 355(b)(1) as the relevant provision, the Court does so as well.

[5] The FDA regulations further define a drug product as "a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." 21 C.F.R. § 314.3.

the compound pioglitazone—alone—while the drug product claims of the Patents are directed to a composition comprised of pioglitazone—in combination with other compounds—those drug product claims do not "claim" ACTOS.

Takeda, by contrast, reads the word "claims" in § 355(b)(1) more broadly, in light of the neighboring phrase "with respect to which a claim for infringement could reasonably be asserted." Under its reading, in order for a patent to be properly described as a "drug product" for an NDA drug, one of the patent's drug product claims must be directed to at least a component of the drug, such that the unauthorized sale of the NDA drug would infringe the claim (either directly or indirectly). That is, according to Takeda, the statute's reference to a patent that claims a drug "*with respect to which a claim for infringement could reasonably be asserted*"—contextualizes the two preceding phrases "claims a method of using such drug" and "claims the drug." Since the label for ACTOS encourages its use in conjunction with the other compounds claimed as part of the Patents' drug product claims (i.e., metformin and insulin secretion enhancers, *see* Dkt. 102-3 at 13), Takeda argues that an unauthorized seller of ACTOS would induce infringement of the patents' drug product claims. According to Takeda, then, because the drug product claims include at least a component of ACTOS, and because infringement of these claims could reasonably be asserted against the unauthorized sale of ACTOS, those drug product claims "claim" ACTOS within the context of § 355(b)(1).

There is another reading, however, that neither party has urged. This reading was articulated by the Federal Circuit in *Apotex, Inc. v. Thompson*, a case which neither party cites. 347 F.3d 1335, 1343 (Fed Cir. 2003). Under this reading, the first use of the term "claims" in § 355(b)(1)—that the listed patent "claims the drug"—requires, as EPPs argue, that at least one of the patent's claims "reads on" the NDA drug, that is, includes the same set of elements. But the

second use of the term "claims"—that the listed patent "*claims* a method of using such drug"—requires, as Takeda argues, only that the patent include a method claim "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Put another way, under this third reading, the phrase "with respect to which a claim of patent infringement could reasonably be asserted" modifies only the directly preceding phrase "claims a method of using such drug," and not the earlier phrase "claims a drug." As explained in further detail below, it is this reading that the Court has concluded must govern.

2. The Plain Meaning of "Claims"

Interpreting the listing statute begins with its text. *See United States v. Lucien*, 347 F.3d 45, 51 (2d Cir. 2003). The meaning of the term "claims" is, unfortunately, not defined in the Hatch Waxman Act ("the Act"). In the absence of such a definition, EPPs are correct that an examination of the plain meaning of the term "claims" is the appropriate starting point. *See United States v. Balde*, 927 F.3d 71, 75 (2d Cir. 2019).

The plain meaning of "claims" in patent law is helpfully illuminated by the Federal Circuit in *Hoeschst-Roussel Pharmaceuticals, Inc. v. Lehman,* upon which EPPs principally rely. 109 F.3d 756 (Fed. Cir. 1997) ("*Hoeschst*"). As explained in *Hoeschst*, the plain meaning of "claims" represents the portion of a patent that delineates the patent owner's property rights in the invention: "[a] claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention." *Id.* at 758. (quoting *Corning Glass Works v. Sumitomo Elec. U.S.A. Inc.*, 868 F.2d 1251, 1257–58 (Fed. Cir. 1989)). The court went on to consider the relationship between the concepts of what a patent claims, and what infringes a patent. While "the claims define the patent owner's property rights,"

"infringement is the act of trespassing upon those rights . . . and, as a result, the plain meaning of 'claims' is not the same as the plain meaning of infringement." *Hoescht,* 109 F.3d at 759.

In light of the Federal Circuit's explicit distinction between the plain meaning of "claims" and "infringement," EPPs logically argue that: (1) the term "claims" in § 355(b)(1) must have a meaning distinct from the term "infringement"; and (2) because Takeda defines a patent that "claims a drug" with respect to that which would reasonably infringe the claim, Takeda's interpretation of "claims" is synonymous with "infringement"—contrary to the plain meaning of "claims" as expounded in *Hoeschst*. Simply put, EPPs maintain that, in § 355(b), the plain meaning of "claims" governs—both as to whether a patent "claims the drug" at issue or "claims a method of using such drug."

3. The Infringement Meaning of "Claims"

In *Hoeschst,* however, the Federal Circuit noted that Congress may, at times, depart from using the word "claims" in accordance with its plain meaning and instead use the word "claims" in accordance with infringement. As Judge Newman highlighted in her concurrence, the words "claim" and "infringe" "are indeed different" but "the distinctions are relevant in appropriate contexts." *Id.* at 764 (Newman, J., concurring). Indeed, "[u]ltimately, context determines meaning." *See Johnson v. United States*, 559 U.S. 133, 139 (2010).

A comparison of the statute at issue in *Hoeschst* and in this case is instructive on how "claims" may be defined with respect to either its plain meaning, or with respect to what may infringe the claim at issue. *Hoeschst* concerned the meaning of the word "claims" in the patent restoration statute, 35 U.S.C. § 156. That statute provides that "[t]he term of a patent *which claims* a product . . . shall be extended . . . from the original expiration date of the patent" in certain

circumstances, such as when "the product has been subject to a regulatory review period before its commercial marketing or use." 35 U.S.C. § 156 (emphasis added).

At issue in *Hoeschst* was whether the life of a patent directed to the chemical compound, 1-hydroxy-tacrine, could be extended under 35 U.S.C. § 156, based on the regulatory review period for the drug, tacrine hydrochloride. The patentee asserted that the patent claiming 1-hydroxy-tacrine necessarily claimed tacrine hydrochloride, because the former is metabolized into the latter when ingested. *See Hoeschst*, 109 F.3d at 759 (recognizing that infringement may occur when the administered product is converted *in vivo* into the claimed product). In other words, similar to Takeda here, the patentee there argued that the patent "which claims a product" in 35 U.S.C. § 156(a), was "any patent that has claims that are infringed by the making, using, or selling of an FDA-approved product." *Id.* But the Federal Circuit rejected that view, concluding that the patentee had not made a "sufficiently strong showing to warrant a deviation from the plain meaning" of "claims." *Id*. at 760. "[H]ad Congress intended the usage urged by [the patentee]," the Court reasoned, "it could have drafted section 156(a) to make that intention more clear," by stating: "[t]he term of a patent which claims a product, a method of using a product, or a method of manufacturing a product *which claim is infringed by an FDA-approved product, use of an FDA-approved product, or manufacture of an FDA-approved product shall be extended. . . .*" *Id.* at 761 (emphasis in original). "Such a statute would clearly indicate that the patent . . . need only claim a product or method of using that product, so long as that claim is infringed by the FDA-approved product or its use." *Id*. at 760–61.

By comparison, the listing statute, 21 U.S.C. § 355(b)(1), is, to some extent, more like the hypothetical statute contemplated in *Hoeschst*—in which Congress would have intended the meaning of "claims" to be defined with respect to infringement—than the patent restoration

statute. Section 355(b)(1) describes a patent which "claims the drug for which the applicant submitted the application or which claims a method of using such drug and *with respect to which a claim of patent infringement could reasonably be asserted*." (emphasis added). Evidently, unlike the patent restoration statute, 35 U.S.C. § 156(a), the listing statute explicitly refers to the concept of what a patent "claims" in the context of infringement. Pursuant to the reasoning of *Hoeschst*, then, Takeda argues that Congress' deliberate choice to use the word "claims" in conjunction with the word "infringement," in the listing statute, demonstrates its intent to define the word "claims" with reference to what infringes a claim, rather than its plain meaning. Simply put, Takeda urges that, in § 355(b)(1), the infringement definition of "claims" governs—both as to whether a patent "claims the drug" at issue or "claims a method of using such drug."

4. *Apotex* Suggests that the Infringement Clause Refers Only to Method-of-Use Claims

The parties do not address the possibility that the plain meaning of "claims" applies in the phrase "claims the drug," while the infringement meaning applies in the phrase "method of using such drug." But *Apotex, Inc. v. Thompson* nonetheless suggests that this is the proper construction of "claims" in the listing statute. 347 F.3d 1335 (Fed. Cir. 2003). There, the Federal Circuit interpreted the identical language in § 355(c)(2) which, as noted, appears to be the provision pursuant to which Takeda originally submitted the Patents' descriptions to the FDA, and which in any event is indistinguishable from § 355(b)(1), as relevant here.

In *Apotex*, the generic sought an injunction requiring that the FDA de-list certain patents from the Orange Book for not satisfying the requirements of § 355(c)(2). In dispute was whether the interpretation of this provision was an issue of patent law under 28 U.S.C. § 1338, over which the Federal Circuit has exclusive jurisdiction to hear appeals from district courts. In deciding this issue, the court elaborated on what the language of § 355(c)(2) requires. The court stated:

> Under [355(c)(2)], a patent must be listed if it contains a product claim that reads on the drug that is the subject of the NDA or, with respect to a method of use claim, if it is reasonable to conclude that a person who makes, uses, or sells the drug would infringe the claim.

Apotex, Inc., 347 F.3d at 1344. The court again stated that to demonstrate the NDA holder's listing was inaccurate:

> Apotex would have to establish that one or more of the patents . . . submitted for listing in the Orange Book claims neither the drug that is the subject of [the relevant] NDA nor a method of using that drug with respect to which a claim of patent infringement could reasonably be asserted against a party who made, used, or sold the drug.

Id. These passages indicate that, in the Federal Circuit's view, the phrase "with respect to which a claim of patent infringement could reasonably be asserted" modifies the term "claims" as used only in the immediately preceding phrase "claims a method of using such drug." With respect to the earlier phrase referring to when a patent "claims the drug," such a patent will do so when it "reads on the drug that is the subject of the NDA"—that is, every element in one of the patent's claims is present in the NDA drug. *See Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002) (noting that a claim limitation "'reads on,' *or in other words is found in*, the accused device" in describing literal infringement) (emphasis added); *de Graffenried v. United States*, 20 Cl. Ct. 458, 476 (Fed. Cl. 1990) (explaining that a claim "reads on" an accused product when it "contains each and every element and limitation called for in the claim").

The above passages from *Apotex* are dicta. The Federal Circuit also did not further explain why it appeared to treat the reference to infringement in § 355(c)(2) as distinctly applying in the phrase "methods of claiming such drug." But considering this interpretation in the context of the parties' respective readings of § 355(b)(1), as analyzed further below, compels the conclusion that it is correct.

5. EPPs' Reading of "Claims" Cannot Apply to Method-of-Use Claims

EPPs apply a plain meaning reading of "claims" as to both uses of the term in § 355(b)(1). But doing so is inconsistent with EPPs' own position that the Patents are properly described as method of use patents, for the reasons explained in this section. As such, the plain meaning of "claims" cannot apply in the phrase "which claims a method of using such drug" in § 355(b)(1).

If the term "claims" in § 355(b)(1) is interpreted in accordance with its plain meaning, EPPs are correct that, to claim ACTOS, a drug product claim must be directed to pioglitazone by itself—not pioglitazone in combination with other compounds. The Supreme Court established that proposition in *Aro Manufacturing. Co. v. Convertible Top Replacement Co.* ("*Aro*"), stating that a "combination patent covers only the totality of the elements in the claim and that no element, separately viewed, is within the grant." 365 U.S. 336, 344 (1961). Crucially, however, this principle also applies with equal force to method claims. That is arguably apparent from *Aro* itself which does not distinguish between product claims and method claims. In any event, it is indisputably apparent from the Supreme Court's more recent decision in *Limelight Networks, Inc. v. Akamai Technologies., Inc.*, which specifically addressed method claims. 572 U.S. 915 (2014). There, in explaining what "[a] method patent claims," the Court relied upon the very quote above from *Aro*, reiterating that a "patentee's rights extend only to the claimed combination of elements and no further." *Id.* at 921. Thus, pursuant to the plain meaning of "claims," a combination drug product claim does not "claim" the individual elements of the drug product—and a combination method-of-use claim does not "claim" the individual methods of the combination. *See id.* (citing *Aro*, 365 U.S. at 344).

Under EPPs' plain meaning interpretation of "claims," it follows that the Patents' method-of-use claims do not claim methods of using ACTOS; rather, they claim methods of using ACTOS

in combination with metformin or an insulin secretion enhancer. This, in turn, necessitates the conclusion that it would be improper or false for the Patents to be listed as methods-of-use patents for the ACTOS NDA. But EPPs unequivocally do not take that position. On the contrary, they contend that the Patents *are* correctly listed as method of use patents that "claim" methods of using ACTOS—even though not one of the Patents' method claims are directed to a method of using ACTOS by itself. EPPs provide no explanation for this discrepancy and the Court does not independently discern one. The plain meaning of claims, therefore, cannot apply both with respect to drug product claims and method-of-use claims.

6. Takeda's Reading of "Claims" Cannot Apply to Drug Product Claims

While Takeda's infringement interpretation of claims makes sense with respect to method-of-use claims, applying it to the drug product claims does not. Requiring the Patents to be described as drug product Patents, when a claim for induced infringement of the *product* claims could reasonably be asserted against the unauthorized sale of ACTOS, is contrary to the language in the Federal Circuit's *Apotex* decision, well-established cannons of statutory interpretation, and FDA regulations.

First, defining the phrase "claims the drug" in § 355(b)(1) with respect to that which would directly or indirectly infringe the corresponding patent claim is contrary to the Federal Circuit's reading of the relevant language in *Apotex.* As previously explained, in that case, the court interpreted the identical language in § 355(c)(2) to mean that "a patent must be listed if it contains a product claim that reads on the drug that is the subject of the NDA *or*, with respect to a method of use claim, if it is reasonable to conclude that a person who makes, uses, or sells the drug would infringe the claim." 347 F.3d at 1344 (emphasis added). This statement reflects that, in the Federal Circuit's view, patents with drug product claims are treated differently than patents with method-

of-use claims in the context of the listing requirements. The former must be listed when the drug product claims read on the drug; the latter must be listed when the method-of-use claims could reasonably be infringed by the unauthorized manufacture, sale, or use of the drug. Applying the infringement meaning of "claims" to both uses of the word in § 355(b)(1), as Takeda urges, is thus contrary to the *Apotex* court's reading of it.

Second, Takeda's interpretation runs counter to the canon against surplusage. Under this canon, "courts must give effect to all of a statute's provisions 'so that no part will be inoperative or superfluous, void or insignificant.'" *United States v. Harris*, 838 F.3d 98, 106 (2d Cir. 2016) (quoting *Corley v. United States*, 556 U.S. 303, 314 (2009)). Here, however, by defining the phrase "claims the drug" with respect to that which would reasonably infringe the relevant patent claim, Takeda's reading renders the phrase "claims the drug" redundant. If Congress intended the infringement meaning of "claims" to apply *both* to drug product and method-of-use claims, then § 355(b)(1) could simply state that a patent must be listed if it contains a claim for which a reasonable claim of patent infringement could be asserted against the unauthorized manufacture, sale, or use of the NDA drug. Instead, the provision distinguishes between a patent that "claims a drug" on the one hand, and a patent that claims a "method of using such drug" on the other. This supports the view that the reference to infringement applies only to method-of-use claims, as opposed to drug substance or product claims—otherwise, the distinction between the two types of patents is superfluous.

Third, Takeda's reading arguably runs counter to the last antecedent rule. Under that rule, "a limiting clause or phrase . . . should ordinarily be read as modifying only the noun or phrase that it immediately follows." *Lockhart v. United States*, 136 S. Ct. 958, 962–963 (2016) ("[Q]ualifying words or phrases modify the words or phrases immediately preceding them and not

words or phrases more remote, unless the extension is necessary from the context or the spirit of the entire writing[.]" (quoting Black's Law Dictionary 1532–1533 (10th ed. 2014))). Applying this principle to § 355(b)(1), the phrase "and with respect to which a claim of patent infringement could reasonably be asserted" is best interpreted as modifying only the immediately preceding phrase "claims a method of using such drug"—not the further preceding phrase "claims a drug." Although the last antecedent rule is typically applied when a modifier appears at the end of a list, *see Lockhard*, 136 S. Ct. at 963, its application here is nonetheless consistent with the Federal Circuit's reading in *Apotex*. *See Apotex*, 347 F.3d at 1344 (restating the language of the listing statute to apply the phrase concerning infringement with respect to method-of-use claims only).

At oral argument, Takeda asserted that its interpretation still gives independent meaning to the phrase "claims the drug." *See* Oct. 23, 2018 Hr'g Tr. at 55:11–56:8 (Dkt. 270). As an example, it said to consider a patent claim directed to a drug's packaging, a drug's metabolite, or a drug's manufacturing process. According to Takeda, those claims could reasonably be asserted against the unauthorized use of the drug, but they do not "claim the drug" because they do not have "anything to do with the drug itself." *Id.* at 55:24–56:2. Takeda's theory thus appears to be that the phrase "claims the drug" is intended to ensure that the patent claim is one that has at least something "to do with the drug." But this distinction is arbitrary. Contrary to Takeda's contention, a metabolite patent, for instance, could easily be understood as having something "to do with the drug" since, by definition, the drug literally becomes the metabolite when ingested by the user. *See Hoechst*, 109 F.3d at 759. A process patent can also be easily understood as something having "to do with the drug" because its claims are directed to a process that produces the drug itself. The Court is thus persuaded that applying the infringement meaning of claims to both drug product claims and method-of-use claims renders the provision's distinction between the two superfluous.

Additionally, the fact that the regulations prohibit the listing of patents directed to packaging or metabolites further supports the conclusion that the infringement meaning of claims does not extend to the phrase "claims the drug." As Takeda acknowledges, a claim directed to a drug's packaging, manufacturing process, or a metabolite could reasonably be asserted against the unauthorized sale of the drug under direct or indirect infringement theories. But at least in the FDA's view, such patents are not to be listed in the Orange Book. Under 21 C.F.R. § 314.53(b)(1), "[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not covered" by the listing requirements and "information on these patents must not be submitted to [the] FDA." That determination is consistent with the notion that those patents do not "claim" the NDA drug at issue; otherwise they would not be prohibited from being listed.

Lastly, while the two other circuit court cases that have touched on the issue arguably support Takeda's reading, they are ultimately unpersuasive. In the first, *aaPharma Inc. v. Thompson*, the Fourth Circuit stated in a footnote that while it would "not explain the statutory criteria [of 21 U.S.C. § 355(b)(1)] in any detail . . . the general idea is that a patent claims a drug under 21 U.S.C. § 355(b)(1) if the patent might be infringed by a generic version of that drug." 296 F.3d 227, 231 n.1 (4th Cir. 2002). Although that statement does not limit the concept of infringement to method claims only, its significance is undermined by the fact that (1) it is explicitly intended to provide only a "general idea" rather than a precise determination of the meaning of claims; and (2) insofar as infringement is relevant to method claims in the context of § 355(b), the statute's text makes clear that the question is whether unauthorized sale of the NDA drug—not a proposed generic thereof—would infringe the claim, contrary to what the statement suggests. *See* § 355(b)(1); *Apotex*, 347 F.3d at 1344. In the second, *Teva Pharmaceuticals, USA, Inc. v. Leavitt*, the D.C. Circuit noted that 21 U.S.C. § 355(b) "requires NDA holders to ascertain

if, under substantive patent law, any patents claim the drug for which the NDA holder submitted an application and then provide FDA with patent information for *any drug which falls within the scope of a patent's protection*." 548 F.3d 103, 106 (D.C. Cir. 2008) (emphasis added). The Court agrees with Takeda that the phrase "within the scope of a patent's protection" is best understood "as a reference to the range of reasonable claims of infringement." Def's Mem. at 11–12. But similar to the *aaiPharma* case, the D.C. Circuit's use of that phrase in interpreting § 355(b) occurred informally in one passing sentence; the focus of that court was on the meaning of a different provision under the Hatch Waxman Act, not § 355(b)(1). Accordingly, Takeda's reliance on these cases is not persuasive.

7. The Two Uses of "Claims" in § 355(b)(1) Have Discrete Meanings

In summary, several factors point to the conclusion that the plain meaning of "claims" in § 355(b)(1) applies in the phrase "claims the drug," but the infringement meaning of "claims" applies in the phrase "claims a method of using such drug." First, only that reading is consistent with the Federal Circuit's articulation of the previous language used in the related provision, § 355(c)(2). *See Apotex*, 347 F.3d at 1344. Second, although there is a presumption that the plain meaning of "claims" applies, *see Hoeschst*, 109 F.3d at 759, if the plain meaning of "claims" applied in both phrases, as EPPs suggest, then it would be improper to describe the Patents as method-of-use patents, even though the propriety of those descriptions is undisputed. Third, the phrase "claims a method of using such drug" is immediately followed by the phrase "with respect to which a claim of patent infringement could reasonably be asserted[.]" This strongly supports the view that Congress intended the word "claims" to be defined by infringement, because it placed the two concepts directly next to one another, similar to the hypothetical statute contemplated in *Hoeschst*. The infringement meaning of "claims" must, therefore, apply in the phrase "claims a

method of using such drug." But contrary to Takeda's suggestion, the "infringement" meaning of claims cannot also apply in the earlier phrase "claims a drug." If it did, it would render the language distinguishing the two types of patents superfluous. Furthermore, it would be inconsistent with FDA regulations prohibiting the listing of processing, manufacturing, and metabolite patents. In the Court's view, the reading suggested in *Apotex* is thus the most sensible reading to apply here. Pursuant to § 355(b)(1), an NDA applicant is required to describe a patent as a drug product patent if it claims the NDA drug, that is, it literally reads on the drug pursuant to the plain meaning of "claims." And the applicant is required to describe a patent as a method-of-use patent if it claims a method in the sense that a reasonable claim of patent infringement could be asserted, with respect to that claim, against the unauthorized manufacture, sale, or use of the drug for which the NDA was submitted.

Because it is not disputed that the Patents' drug product claims do not literally read on ACTOS, EPPs have plausibly alleged that Takeda's 2010 statements to the FDA were inaccurate.

II. EPPs Need Not Allege Bad Faith

Takeda next argues that even if the Court were to disagree with its interpretation of § 355(b)(1), it must still find that EPPs have plausibly alleged that Takeda's interpretation was made in bad faith, in order for EPPs to adequately plead anti-competitive conduct. The Court disagrees.

A. Bad Faith is Not an Element of a *Prima Facie* Case for Monopolization Pursuant to the Rule of Reason

As previously noted, to prevail on a monopolization claim pursuant to § 2 of the Sherman Act, a plaintiff must establish "the possession of monopoly power in the relevant market," and "the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historical accident." *In re Adderall*

XR Antitrust Litig., 754 F.3d at 133. In evaluating such claims, the Second Circuit applies the so-called "rule of reason" framework in the manner set forth by the D.C. Circuit in *United States v. Microsoft Corp.*, 253 F.3d 34, 58–60 (D.C. Cir. 2001). *See Schneiderman*, 787 F.3d at 652. Pursuant to the rule of reason, the plaintiff must first establish "that a monopolist's conduct is anticompetitive or exclusionary." *Id.* The burden then shifts to "the monopolist [who] may proffer 'nonpretextual' procompetitive justifications for its conduct." *Id.* If a defendant meets its burden, the burden shifts back to the plaintiff who may then either "rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit." *Id.*

Nothing in the rule of reason suggests that a plaintiff must plead defendant's bad faith to meet its initial burden of establishing anti-competitive conduct. Indeed, in other contexts, plaintiffs have adequately alleged anti-competitive conduct without pleading such bad faith. *See, e.g.*, *id.* at 652–654 (finding that defendants' introduction of one drug product into the market while simultaneously withdrawing another product constituted anti-competitive conduct warranting a preliminary injunction because it effectively coerced purchasers into purchasing the newer product); *Savory Pie Guy, LLC v. Comtec Indus., Ltd.*, No. 14-CV-7527 (VB), 2016 WL 7471340, at *10 (S.D.N.Y. Dec. 28, 2016) (finding, on motion for summary judgment, that plaintiff raised triable issues of fact as to whether defendant's alleged refusal to deal with customers that purchased certain equipment from defendant's competitors constituted anti-competitive conduct).

It is true, as Takeda argues, that EPPs have not identified any case in which a court held that bad faith was *not* an element of a monopolization claim predicated on a wrongful Orange Book listing. But in a related context, at least one court has denied a motion to dismiss monopolization claims, without making any assessment as to whether the defendants had a good

faith basis for their conduct. In *In re Neurontin Antitrust Litigation*, the plaintiffs successfully stated monopolization claims against the defendant based on allegations of an "overall scheme to monopolize." MDL No. 1479, 2009 WL 2751029, at *14–16 (D.N.J. Aug. 28, 2009). The alleged conduct comprising the scheme included the defendant's decisions to list patents in the Orange Book improperly, to manipulate the prosecution of one of those patents, and initiate sham lawsuits, among other things. But the court made no determination as to whether the defendant had a good faith basis for the allegedly improper Orange Book listing, concluding that the conduct, as a whole, adequately alleged claims for monopolization and attempted monopolization. Although the conduct at issue in EPPs' case is focused exclusively on Takeda's Orange Book listings, nothing in *In re Neurontin* suggests that this distinction would require a plaintiff to plead that the conduct was made in bad faith.

In short, then, there is no reason to presume that, under the rule of reason, a defendant's purported good faith belief that its conduct was necessary is part of a plaintiff's *prima facie* case.

B. Takeda Fails to Establish that EPPs Must Plead Bad Faith in this Case

Takeda's efforts to persuade the Court otherwise are not persuasive. As noted, Takeda contends that a plaintiff cannot allege that a defendant's conduct was anticompetitive when the conduct is premised on a good faith effort to comply with a mandatory statute. In support of this theory, it relies upon two out-of-circuit cases: *Phonetele, Inc. v. American Telephone & Telegraph Co.*, 664 F.2d 716, 737 (9th Cir. 1981), *modified*, Nos. 77-3877, 77-2936, 1982 WL 11277 (9th Cir. Mar. 15, 1982), and *Southern Pac. Commc'ns Co. v. Am. Telephone & Telegraph Co.*, 740 F.2d 980, 1009 (D.C. Cir. 1984). But neither case suggests, as Takeda argues, that a plaintiff is required to prove, as part of its *prima facie* case alleging monopolization, that a defendant's failure to comply with a complicated regulatory scheme was made in bad faith. Rather, these decisions

are clear that, to the extent a defendant accused of anticompetitive conduct asserts that the conduct was based on a good faith interpretation of binding regulations, that is a *defense* to an antitrust claim.

The claims in *Phonetele* and *Southern Pacific*, which, like here, included monopolization claims, arose in part from tariffs filed with the Federal Communications Commission (the "FCC") by the defendants who were telecommunication carriers. The tariffs at issue in *Phonetele* "prohibited the direct electrical connection of customer-provided equipment to the telephone without the use of a plate-like connecting device . . . supplied by the telephone company." 664 F.2d at 720. They were imposed in response to an FCC decision finding that tariffs concerning such connection devices should not ban the devices altogether but "should be designed only to prohibit devices dangerous to the system." *Id.* at 726. In rejecting the defendant's assertion that it was entitled to antitrust immunity with respect to the tariff at issue, the court held: "[i]f a defendant can establish that, at the time the various anticompetitive acts alleged here were taken, it had a reasonable basis to conclude that its actions were necessitated by concrete factual imperatives recognized as legitimate by the regulatory authority"—for example, that the defendant "reasonably conclude[d] . . . that uncontrolled . . . interconnection would endanger their own equipment"—"then its actions did not violate the antitrust laws." *Id.* at 737–38. The court further reasoned that "[t]he logic of complying with a regulatory mandate is relevant as an antitrust *defense* but the same logic has internal limits which do not justify any and all acts ostensibly taken in response to the" relevant statute or regulations. *Id.* at 743. And in *Southern Pacific*, which relied on *Phonetele*, the court observed that "this regulatory justification defense is only applicable if [the defendant's] asserted 'public interest' basis for its interconnection decision [was] reasonable and if [the defendant] actually made its decision at the time in good faith on that basis rather than solely on

the basis of competitive considerations." 740 F.2d at 1009. A review of these cases suggests that a highly regulated defendant can seek to avoid antitrust liability by asserting a defense that it acted in good faith to comply with a regulatory mandate but such a defense is factual in nature—not something to be addressed at the motion to dismiss stage.

At oral argument, Takeda conceded that *Southern Pacific* and *Phonetele* describe an entity's good faith effort to comply with regulations as an affirmative defense to antitrust claims. Oct. 23, 2019 Hr'g Tr. at 19:22. It nonetheless tried to distinguish those cases on the ground that those plaintiffs were challenging the defendants' conduct towards them directly—that is, the imposition of tariffs on the plaintiffs—whereas here, EPPs are challenging Takeda's "actions in front of the FDA itself, not something [Takeda] did to them[.]" *Id.* at 18:14–17. Takeda contends that in the former scenario, if a defendant asserts that the conduct was consistent with mandatory regulations, that is an affirmative defense. *Id.* at 19:7–13. But in the latter scenario, Takeda asserts that the plaintiffs must show that the conduct was not reasonable as part of their *prima facie* case.

This distinction, however, is not, as Takeda put it, "subtle, rather, it is artificial. First, at least under EPPs' theory of this case, Takeda's conduct can just as easily be characterized as conduct directed to the generics, and EPPs by extension, to the extent it caused the FDA to require the generics to submit Paragraph IV certifications, and delayed generic entry as a result. Conversely, in the telecommunication cases, the common carriers' conduct in imposing tariffs could just as easily be characterized as actions in front of the FCC, since the carriers had to first file their tariffs with the agency in order to implement them. *See Phonetele*, 664 F.2d at 724–25. In other words, Takeda's suggestion that *Phonetele* and *Southern Pacific* did not involve "some regulatorily required act," (Oct. 23, 2019 Hr'g Tr. at 19:2) unlike this case, is unpersuasive. The common carriers were required to make a regulatory submission to an agency (i.e., file tariffs with

the FCC) if they wanted to impose them. By the same token, if Takeda wanted to market a brand drug it too was required to make a regulatory submission to an agency (i.e., file an NDA with the FDA). In the telecommunication cases, the regulatory scheme governed the lawfulness of the submission. If plaintiffs alleged that portions of the submission (i.e, the parameters of the tariff) were anti-competitive, then the carriers—as a defense—could assert in good faith that they reasonably believed that their submission complied with the law. Invoking those cases here, as Takeda has, if EPPs believe that part of Takeda's NDA was anti-competitive, then Takeda—as a defense—can also assert that it made a good faith effort to comply with the law. In short, Takeda's reliance on *Phonetele* and *Southern Pacific* does not establish that EPPs are required to plead bad faith to state their monopolization claims against Takeda.

Nor does Takeda's reliance on the various district court cases it cites establish that bad faith is an element of EPPs' monopolization claims. Two of those cases dealing with Orange Books did not involve the legal theories at issue here. *See Astra Aktiebolag v. Kremers Urban Dev. Co.*, Nos. 99-CV-8928(BSJ), 99-CV-9888(BSJ), 2001 WL 1807917, at *1 (S.D.N.Y. Oct. 26, 2001) (dismissing defendant's counterclaim of patent misuse, based on the patentee having listed certain patents in the Orange Book and asserted them against defendant, for failing to adequately allege bad faith or improper purpose); *Kroger Co. v. Sanofi-Aventis*, 701 F. Supp. 2d 938, 964 (S.D. Ohio 2010) (dismissing a monopolization claim, premised on the theory that the defendant instituted sham litigation against its generic competitors, to preclude competition, for failing to allege that the lawsuits were "subjectively and objectively baseless"). While it is true that the claims in those cases could not be sustained for failing to allege bad faith, that is because bad faith was indisputably a required element to state a claim for patent misuse and sham litigation. These cases are thus inapposite on the issue of whether bad faith is an element of EPPs' monopolization claims.

Takeda's reliance on two additional cases—*Organon Inc. v. Mylan Pharmaceuticals, Inc.*, 293 F. Supp. 2d 453, 460 (D.N.J. 2003), and *In re Lantus Direct Purchaser Antitrust Litigation.*, 284 F. Supp. 3d 91 (D. Mass. 2018)—provide better support for its position on this issue, but they do not ultimately persuade the Court that EPPs must plead bad faith. In *Organon*, the defendant had listed a patent under § 355(c)(2) as claiming methods of using the anti-depressant drug, mirtazaprine. 293 F. Supp. 2d at 455–56. The patent claimed only methods of using mirtazaprine in combination with other compounds. *See id.* The plaintiffs asserted that the listing was improper—not because the patent claimed only combination uses—but because, unlike Takeda here, the defendant had not obtained FDA approval for those uses. According to the plaintiffs, § 355(c)(2) and supporting regulations did not permit the listing of method patents claiming uses that had not been FDA-approved (otherwise known as "off-label" uses). *Id.* at 459. The plaintiffs asserted a monopolization claim against the defendant on that basis. In analyzing the claim, the court quoted the language of a regulation addressing the listing of method patents, 21 C.F.R. § 314.53(b). *Id.* at 460. It then concluded in summary fashion that (1) § 314.53(b) was capable of "two equally plausibly interpretations" (the two urged by the parties); and (2) the plaintiff "had a reasonable basis for the submission, and therefore, [its] listing was not improper." *Id.* at 460–61.

Nothing in *Organon*, however, explains the legal basis for that conclusion. The *Organon* court cites no authority, and it does not appear to articulate a rationale as to why the reasonableness of the defendant's interpretation precluded the plaintiff from stating a monopolization claim. In the absence of more reasoning to support the court's conclusion, this Court respectfully declines to apply it here.

Citing *Organon*, the *Lantus* court similarly held in conclusory fashion that the plaintiffs could not state a monopolization claim against an NDA holder, predicated on an allegedly

improper Orange Book listing, where the defendant's interpretation of the listing statute was reasonable. 284 F. Supp. 3d at 94–95. There, the defendant NDA-holder had listed a patent on a drug delivery device (a disposable injector pen) with respect to an NDA on a drug called insulin glargine. Although the patent did not reference insulin glargine, the injector device that it recited was "sold loaded with a dosage of insulin glargine." *Id.* at 99. The plaintiffs alleged that the listing was improperly made, intended to extend the patent life on the insulin glargine drug substance. The defendant responded that the listing was proper in light of FDA guidance at the time concerning drug-delivery devices. The court held that the defendant's interpretation of the relevant FDA regulation was "not unreasonable" and dismissed the complaint because the plaintiffs had not "pled sufficient facts to establish that [the defendant's] decision to list the [drug delivery device patent] was unreasonable *or objectively baseless.*" *Id.* at 105 (emphasis added).

The Court is also not persuaded by the reasoning in *Lantus.* As with *Organon*, the *Lantus* court does not support its holding—that the plaintiffs were required to plead that the defendant's interpretation of the FDA's regulations was unreasonable—with pertinent legal authority. Second, by stating that the defendant's Orange Book listing was not "objectively baseless," the *Lantus* court appears to have applied the legal standard that governs the "sham litigation" exception to *Noerr-Pennington* immunity—something indisputably not at issue here—to listing claims.

The *Neorr-Pennington* doctrine, among other things, immunizes private actors from antitrust liability for conduct that constitutes "petitioning activity" aimed at "persuading the government of a position or expressing views and wishes concerning government decisions." *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07-CV-7343(HB), 2008 WL 169362, at *1, *3 (S.D.N.Y. Jan. 18, 2008) (citing *E. R.R. Presidents Conference v. Noerr Motor Freight Inc.*, 365 U.S. 127 (1961) and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965)). "The doctrine

was first established in the context of concerted petitions for anti-competitive legislation," but the Supreme Court later extended it to the petitioning of courts and administrative bodies through good faith litigation. *Primetime 24 Joint Venture v. Nat'l Broad, Co.*, 219 F.3d 92, 99 (2d Cir. 2000). A patentee who seeks to enforce its patent through litigation, however, can lose *Noerr-Pennington* immunity if: (1) the patent was obtained through fraud, or (2) the litigation is a "mere sham" meaning it is "objectively baseless and subjectively motivated by a desire to impose collateral, anti-competitive injury." *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071 (Fed. Cir. 1998). The court in *In re Buspirone Patent Litigation*, 185 F. Supp. 2d 363, 372–73 (S.D.N.Y. 2002), which is cited in both *Organon* and *Lantus*, held that listing patents in the Orange Book does not constitute petitioning activity that could confer *Noerr-Pennington* immunity (a proposition that neither party here takes issue with at this time). The *In re Buspirone* court nevertheless noted that even *if* Orange Book listing submissions constituted petitioning activity, the plaintiffs in that case sufficiently pled that the "sham litigation" exception to any *Noerr-Pennington* immunity applied. This was because the plaintiffs had stated facts to support that the relevant lawsuit "was objectively baseless."

The *Lantus* court's holding that the plaintiffs were required to show that the defendant's interpretation of the listing statute was "objectively baseless"—supported only by citing *In re Buspirone*—suggests that the court was applying the "objectively baseless" standard used in the *Noerr-Penington* context to the listing statute.[6] The court, however, provided no analysis in support of that decision. For that reason, and because, as with *Organon*, the *Lantus* court also did not articulate its basis for requiring plaintiffs to allege that the defendant's interpretation of its

[6] To be sure, the plaintiffs in *Lantus* had also asserted a separate sham litigation theory, in support of their monopolization claims, with respect to which the court appropriately applied the "objectively baseless" standard. But the court also appears to have applied that standard to the alleged false Orange Book listings.

listing obligations was unreasonable, the Court respectfully declines to apply the holding of *Lantus* in this case.

The Court has not identified any other cases that persuasively reason that a plaintiff is required to prove bad faith as an element of a monopolization claim predicated on an interpretation of a statute or regulation. Nor has Takeda persuaded the Court to conclude as much here. It is true that NDA holders may at times be unsure about their obligations under the listing statute, particularly where there is a dearth of helpful FDA guidance. The Court thus appreciates Takeda's concern that if a plaintiff need not plead bad faith to assert a monopolization claim against an NDA applicant, predicated on an allegedly improper Orange Book listing, the NDA applicant may be forced to expend significant resources in defending itself against possible treble damages, based on a potentially good faith interpretation of a congressional mandate. At the same time, however, the incentive for a brand company not to comply with its listing obligations, as the Supreme Court has recognized, is very real: doing so can extend the brand's monopoly power without direct regulatory consequence because the FDA does not affirmatively police these listings. *See Caraco Pharm. Labs., Ltd. V. Novo Nordisk*, 566 U.S. 399, 424 (2012). In this Court's view, requiring plaintiffs to demonstrate bad faith as part of an antitrust claim, based on an improper listing, fails to strike the appropriate balance between the Hatch Waxman Act's competing policies of incentivizing innovation and expediting generic competition. Placing the burden of demonstrating a good faith effort to comply with mandatory regulations on the purported monopolizer reduces its incentive to construe the Act's listing requirements in a manner contrary to law, in order to extend its monopoly. Were that burden placed on the plaintiffs, it would become easier for an NDA applicant to avoid antitrust liability because of the difficulties plaintiffs face in obtaining the necessary facts to plausibly allege bad faith. In other words, placing the burden on plaintiffs would

not adequately deter NDA applicants from succumbing to their incentive to flout the Act's listing requirements. In any event, doing so is not supported by any binding authority in antitrust law, as previously explained.

Accordingly, the Court is unpersuaded by Takeda's argument that EPPs must plead that its interpretation of the listing statute was made in bad faith. EPPs need not allege that Takeda's improper Orange Book listings were made in bad faith. They have sufficiently pled that Takeda's 2010 statements to the FDA constituted anticompetitive conduct.

III. EPPs Plausibly Allege that the Non-Teva Generics Would Have Withdrawn Their Paragraph IV Certifications as to the Patents' Drug Product Claims

On remand, Takeda does not contest the theory of causation that the Second Circuit embraced as to Teva. As previously explained, the Circuit approved the theory that Takeda's 2010 statements to the FDA, in response to the citizen petition, caused the FDA to cause Teva to file Paragraph IV certifications as to the Patents' drug product claims, which delayed Teva's generic entry (the "Teva theory"). Having now concluded that EPPs have adequately alleged that Takeda's statements to the FDA constituted anti-competitive conduct, EPPs' monopolization claims, to the extent based on the injury caused by Teva's delayed entry into the ACTOS drug market, will proceed.

Takeda does dispute, however, EPPs' application of the Teva theory as to the other generic defendants.[7] Takeda argues that even if its 2010 statements to the FDA were inaccurate, and even if EPPs are not required to plead bad faith to allege that those statements constituted anticompetitive conduct, EPPs still fail to allege that the conduct caused any delay of the other generics' entry into the ACTOS market. The Court disagrees.

[7] That theory, as noted, was not advanced before the Second Circuit but this Court permitted EPPs to include it in their Complaint following remand.

Under the Teva theory as expanded to all generics, EPPs maintain that had Takeda told the FDA that the Patents were improperly described as drug product patents, (which, as the Court has now decided, they were) then the following chain of events would have occurred: (1) either the FDA "would have required all ACTOS generic manufacturers" to address the Patents using "either a Section viii Statement or a Paragraph IV certification, not both," or the generics would have independently withdrawn their Paragraph IV certifications, Compl. ¶ 78; (2) "each of the ACTOS generics with ANDAs containing split certifications" would have amended their ANDAs to address the method-of-use claims, using either a Section viii statement or Paragraph IV certification, *id.* ¶ 79; (3) "[a]s rational profit maximizing entities," the generics "would have elected [s]ection viii [s]tatements exclusively," in light of the litigation triggered by a Paragraph IV certification and the resulting 30-month stay, *id.* ¶ 81; and (4) the generics, with their newly amended Section viii statements, would have been able to enter the market earlier than they did, and without regard to any still-existing 180-day exclusivity periods.

Takeda attacks this theory at the first link in the causal chain. According to Takeda, even if it had told the FDA in response to the citizen petition that the Patents should not be described as drug product patents for the ACTOS NDA, the generics would *still* have been required to maintain their Paragraph IV certifications as to the Patents' drug product claims. But Takeda fails to provide any relevant legal support for this position, which is also contradicted by the facts of this case. EPPs' position to the contrary, by contrast, is consistent with the statutory scheme.

In attempting to rebut the notion that the FDA would have required the generics to withdraw their Paragraph IV certifications as to the Patents' drug product claims, Takeda first cites *Caraco*, 566 U.S. at 406, for the proposition that "[o]nce a patent is listed in the Orange Book, each generic applicant must address the *entire* Patent." Def.'s Mem. at 18. Takeda bases this

proposition on the general statement made by the *Caraco* court in describing the Hatch-Waxman Act, that "[a]fter consulting the Orange Book, a company filing an ANDA must assure the FDA that its proposed generic drug will not infringe the brand's patents." Caraco, 566 U.S. at 406. But this statement cannot reasonably be read to say anything about whether an ANDA applicant must certify as to drug product claims if the NDA holder never described the patent as a drug product patent in the first place.[8] Takeda's argument that an ANDA applicant is required to do so, to the extent it is based on *Caraco*, thus lacks merit.

Next, Takeda cites the FDA's response to a comment on a 2003 rulemaking in which the FDA states that it "concluded that submission of a claim-by-claim declaration for all patents is not warranted," 68 Fed. Reg. 36,676, 36,685 (June 18, 2003). But again, this statement does not address whether an ANDA applicant would have to submit a certification as to drug product claims in a patent that was described in the Orange Book, only as a method-of-use patent, for a particular NDA drug. This statement simply concerns the obligations on the part of the *NDA* applicant in filing an NDA, not the ANDA applicant. It explains that an NDA applicant need not describe the individual claims of a patent and can simply include one description for the entire patent (i.e., "drug product," "drug substance," or "method-of-use") provided that the patent includes at least one such claim. The guidance goes on to explain that, for patents with method-of-use claims, the NDA applicant must describe the use for each method claim so that ANDA applicants can "assess whether they are seeking approval for a use claimed in the listed patent, and thus determine whether to submit a patent certification or a section viii statement." 68 Fed. Reg. at 36,685. The FDA's comment Takeda relies upon is inapposite: it says nothing about whether a generic's

[8] The remainder of *Caraco* stands for the unrelated proposition that generic companies may assert a counterclaim, pursuant to 21 U.S.C. § 355(j)(5)(C), requiring an NDA holder to correct its descriptions of the uses covered by method-of-use claims ("use codes") if those descriptions are inaccurate.

ANDA is prohibited from addressing only a patent's method-of-use claims, when the patent also includes product claims, but is described solely as a method-of-use patent.

The FDA's response to the Sandoz citizen petition, by comparison, is more illuminating. In that response, the FDA explained that "where a patent *is submitted* as claiming both the drug product and a method of using the drug," an ANDA applicant can file a "split certification to that patent, which includes both a paragraph IV certification to the drug product claim and a section viii statement to the method of use and an accompanying label carveout." Weiner Decl., Ex. A at 7. The FDA reiterated that "[t]he ANDA applicant must address all claims *for which the patent was submitted* and may file a paragraph IV certification to some claims and a section viii statement to other claims, as appropriate." *Id.* Thus, if there were claims in a patent for which the patent was *not submitted*, the FDA's response suggests that it would not have required an ANDA applicant to address those claims.

So, too, do the very facts of this case. Prior to the Sandoz Citizen Petition, Teva had submitted Section viii statements *only* as to the method of use claims when it submitted its original ANDA, and had not included any certifications with respect to the drug product claims. The citizen petition response made clear that Teva needed to submit Paragraph IV certifications as to the drug product claims, *specifically because* Takeda had *described* the patent as a drug product patent—not because there was an independent legal obligation to do so. The citizen petition response thus supports the view that had Takeda *not* listed the Patents as drug product patents, Teva would not have been required to file a Paragraph IV certification.

Lastly, this conclusion also has some support in the FDA's response to a comment on the 2003 rulemaking that Takeda cites. There, the FDA stated that "[t]he number of claims contained within a particular patent does not affect the ability of the patent to be listed as long as there is at

least one claim" meeting the listing statute's requirements. 68 Fed. Reg. at 36,685. This suggests that if, as in this case, a patent includes drug product and method claims, but only the method claims meet the required elements for listing, then the listing should not be affected if the patent is described only as a method-of-use patent. By the same token, then, a generic's ANDA should not be affected if it includes an appropriate certification or Section viii statement only as to the listed claims—that is, those that meet the required elements for listing, such as the method-of-use claims in the patents at issue here. *See* 21 U.S.C. § 355(j)(2)(A) (requiring the ANDA applicant to include certifications or a Section viii statement "with respect to each patent . . . for which information is required to be filed under [§ 355(b)(1)] or [§355(c)(2)]"). Additionally, the FDA stated in the same comment that it "decline[d] to adopt [a] recommendation . . . to require all claims to be listed" in the patent information submitted with an NDA (except with respect to method-of-use claims). 68 Fed. Reg. at 36,685. Accordingly, the fact that the FDA did not require every drug product claim in a patent to be listed—which makes sense when those claims do not meet the listing statute's standards—belies the notion that it *would* have required a certification for non-listed drug product claims, as Takeda argues.

Thus, at the very least, EPPs have plausibly alleged that if: (1) Takeda had properly told the FDA that its original patent declaration describing the Patents as drug product patents was inaccurate, by amending its patent information in response to the Sandoz citizen petition to reflect that the Patents covered only methods of using ACTOS, *see* 21 C.F.R. § 314(f)(1), and (2) the FDA, accordingly, revised the Orange Book listing for ACTOS, *see id.*; then the generics would not have been required to maintain their Paragraph IV certifications as to the Patents' drug product claims. In other words, EPPs have plausibly alleged that had Takeda told the FDA the truth, the FDA's ruling on the citizen petition would have been the opposite: Sandoz' request that all

generics be required to submit Paragraph IV certifications as to the drug product claims would have been denied.

Although the non-generics were not parties to the citizen petition, the FDA's ruling was a matter of public record which the generics would plausibly have been following with interest given its potential impact on their own lawsuits and entries into the market. If the FDA had ruled against Sandoz and revised the ACTOS Orange Book listing to reflect Takeda's amended (and truthful) declaration, that outcome plausibly would have led the other generics to withdraw their Paragraph IV certifications as to the Patents' drug product claims. As EPPs explain, the generics would have been faced with the choice of maintaining their Section viii statements as to the Patents' method claims, or revising them to Paragraph IV Certifications. EPPs further plausibly allege that the generics would have elected Section viii statements, as they originally had, so that they could enter the market sooner than they did. Takeda has not contended otherwise. As such, EPPs' monopolization claims—to the extent based on the antitrust injury caused by the delayed entry of the other generics named in the Complaint, into the ACTOS drug market—will also proceed.

Of course, through discovery and after, Takeda will have its opportunity to prove that it reasonably thought that its listing decisions were mandated by statute, and that the delay in generics' market entry would still have occurred absent the improper Orange Book listings. The relevance or significance of Takeda's reasonableness arguments in the rule of reason analysis need not be addressed at this stage of the litigation. Insofar as Rule 12(b)(6) is concerned, EPPs have adequately alleged their monopolization claims.

CONCLUSION

For the foregoing reasons, Takeda's motion to dismiss is DENIED. The Clerk of Court is directed to terminate the motion pending at Dkt. 257.

SO ORDERED.

Dated: September 30, 2019
New York, New York

Ronnie Abrams
United States District Judge